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SC

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/191,915 11/13/98 KARPMAN

R 29763.0100

EXAMINER

QM12/0710

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WOOD, J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED:

07/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/191,915	Applicant(s) Karpman et al.
Examiner Julian W. Woo	Group Art Unit 3731

Responsive to communication(s) filed on 5-1-00

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-5, 7, 10-12, 15, 17-19, and 23-47 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-5, 7, 10-12, 15, 17-19, and 23-47 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

2. An anticipation under 35 U.S.C. 102(b) or 102(e) is established when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention. See RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440, 221 USPQ 385 (Fed. Cir. 1984).

It is well settled that the law of anticipation does not require that the reference teach what appellant is teaching or has disclosed, but only that the claims on appeal "read on" something disclosed in the reference, i.e., all limitations of the claims are found in the reference. See Kalman v. Kimberly Clark corp., 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1083). Moreover, it is not necessary for the applied reference to expressly disclose or describe a particular element or

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limitation of a rejected claim word for word as in the rejected claim so long as the reference inherently discloses that element or limitation. See, for example, Standard Havens Products Inc. v. Gencor Industries Inc., 953 F.2d 1360, 21 USPQ2d 1321 (Fed. Cir. 1991).

3. Claims 1-5, 7, 10, 15, 17, 34, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Spievack et al. (5,871,484). With respect to claims 1-4, 34, and 43, Spievack et al. disclose in figure 3 a device comprising: a head portion, 20, having an injection site, 34; a shaft portion; a cannula, 25 or the continuation of 34; and at least one slot, 24, one slot being proximate to the head portion and one being proximate to the tip portion and each slot having a cross-sectional area greater than the cross-sectional area of the cannula. With respect to claims 5 and 7, Spievack et al. disclose in figures 8 and 9, a device with a means to engage and turn the device at the head portion, which is the screwdriver slot at element 66 or 76, that can also serve as an indicator of the orientation of slot 67 or 77. With respect to claims 10, 15, and 17, they disclose a bone anchoring device or screw with a head portion, 92, with an attachment means for an injection device, 95, and an engagement means (inherent to a screw head); an elongate shaft portion with an external threaded portion and a cannula, a tip and at least one port, 94.

4. Claims 23, 24, 29, 35, 36, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Tronzo (4,653,489). Tronzo in figures 1-4 illustrates the method as claimed. He discloses a method that includes providing a fixation device comprising a bone screw, 36; a plate, 34; and a nail, 32; and a method that includes a detachable delivery device, 46.

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 11, 12, 18, 19, 25, 41, 42, and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spievack et al. (5,871,484) in view of Tronzo (4,653,489). Spievack et al. in figure 12 discloses the invention substantially as claimed. They also disclose in col. 1, lines 22-36, that their device can be used to deliver bone-growth agents. However, they do not disclose an attachment means comprising a threaded recess formed in the head portion, a coupling assembly for attaching a fixation device to the head portion, an adapter device for forcing an anchoring substance through the cannula, and a plug for sealing the cannula. Spievack et al. also do not disclose that their device can be used with a fixation substance to form fixation masses in compliance with the slots of their device. They also do not disclose that the slots deliver a

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fixation substance to inner and outer cortex portions, and they do not disclose a hardening substance or bone cement. Tronzo in figure 1 teaches a bone anchoring device with an attachment means comprising a threaded recess, 48, formed in the head portion; a coupling assembly, 38, for attaching a fixation device, 34, to the head portion and an adapter device, 46, for forcing an anchoring substance through the cannula. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Tronzo, to modify the device of Spievack et al., so that it can be used to inject an anchoring substance into bone. Such modifications would allow introduction of more viscous, therapeutic substances into bone. Tronzo in figure 2 also teaches the delivery of bone cement through slots in his device, where the cement forms fixation masses within bone. It also would have been obvious to one having ordinary skill in the art at the time the invention was made, to use the device of Spievack et al. for the delivery of bone cement through the slots to form fixation masses within bone, and it would have been a matter of design choice to apply the cement to any bone portions requiring fixation, including inner and outer cortices.

Spievack et al. in figure 3 disclose a cap or plug for sealing a cannula. Thus, it would have been obvious to one having ordinary skill in the art to modify the embodiment of figure 12 and include a plug. Such a plug would seal the cannula and prevent the entrance of foreign matter and the escape of an anchoring substance or therapeutic substance from the cannula.

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8. Claims 26-28, 30-33, and 37-39 rejected under 35 U.S.C. 103(a) as being unpatentable over Tronzo. Tronzo discloses the invention substantially as claimed. However, he does not specifically disclose the step of position the slots of his device near cortex portions of the bone or in proximity to an outermost region of a centrum area of the pedicle bone. Nevertheless, it would have been a matter of design choice to apply a fixation substance or bone cement to any bone portions requiring fixation, including cortex portions or the pedicles. It also would have been obvious to one having ordinary skill in the art to position the device within bone, so that the bone cement is disbursed to the desired site via the slots, tip, or openings of the device.

Response to Amendment

9. Applicant's arguments filed on May 1, 2000 have been fully considered but they are not persuasive. The responses regarding the rejection of claims based upon "Spievack" are directed to the intended uses of the invention rather than to structural differences between the invention and the reference devices. Structurally, the invention and the reference devices are the same. Since the invention in the present case is structurally the same as the reference devices, the PTO cannot issue an apparatus claim to an already known device.

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Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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11.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:30 PM Eastern Time.

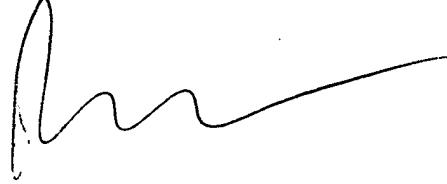
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Buiz, can be reached at (703) 308-0871.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)305-3579.

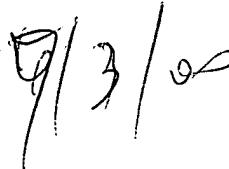


Julian W. Woo

Patent Examiner



MICHAEL BUIZ
SUPERVISORY PATENT EXAMINER
GROUP 3300



July 3, 2000